

REMARKS/ARGUMENTS

The Examiner has rejected claims 3-10, 13 and 14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner alleges that the claims are vague, indefinite and incomplete for the following reasons.

- (a) The recitation of "determining the status of p53 (TP53) gene" (claim 3) is vague and indefinite because the meaning of the term within the context of the claim is not understood. Applicants have amended claim 3 to recite what is meant by the term "status". Support can be found on page 7, second paragraph, of the specification as originally filed.
- (b) The recitation of "genetic status of p53 (TP53) (claim 5) is vague and indefinite because the meaning of the term within the context of the claim is not understood. Applicants have canceled claim 5.
- (c) The recitation of "each subject" (claim 7) is incomplete because there is no antecedent basis for the term. Applicants have amended the claim to read said subjects".
- (d) The recitation of "level of p21 expression" (claim 13 and 14) is vague and indefinite because the meaning of the term within the context of the claim is not understood. Support for the "level of p21 expression" can be found on page 12 of the specification as originally filed.
- (e) The recitation of "enhancing the activity" (claim 14) is vague and indefinite because the instant application does not define what is meant by the term and there is no art-recognized meaning for the term. Applicants have deleted this term.
- (f) The recitation of "therapeutically effective amount" (claim 14) is incomplete because the claim does not indicate with clarity what the therapeutic effect is. Applicants have deleted this term.

Based on the foregoing, Applicants respectfully request that the 35 U.S.C. 112, second paragraph rejection of claims 3-10, 13 and 14 be reconsidered and withdrawn.

Claims 3-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The Examiner alleges that the claims do not recite or result in a transformative result, but merely recite methods of comparison. Applicants respectfully disagree.


Independent claim 3 has been amended to more clearly define the Applicants invention. Further, claim 3 is directed to a method for determining the sensitivity of a proliferative disease in a subject in response to treatment with an mTOR inhibitor and a cytotoxic agent. The sensitivity is determined by the presence of a p53 (*TP53*) gene and/or the level of expression/post-translational modification of p53 in a sample derived from the subject. The determination of the sensitivity and how one can determine the "status" of the p53 gene are defined in the specification on page 7, second paragraph, as originally filed.

Based on the foregoing, Applicants respectfully request that the 35 U.S.C. 101 rejection of claims 3-10 be reconsidered and withdrawn.

No new matter has been added. Should the Examiner have any questions, please contact the undersigned attorney.

Respectfully submitted,

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